UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte STEPHEN A. UDEM, MOHINDERJIT S. SIDHU, and VALERIE B. RANDOLPH

Appeal No. 2005-0196
Application No. 09/508,913

ON BRIEF

Before SCHEINER, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 and 3, which read as follows:

1. An isolated, recombinantly-generated, attenuated, human respiratory syncytial virus (RSV) subgroup B having at least one attenuating mutation in the RNA polymerase gene, wherein the at least one attenuating mutation in the RNA polymerase gene is selected from the group consisting of nucleotide changes which produce changes in an amino acid selected from the group consisting of residues 353 (arginine → lysine), 451 (lysine → arginine), 1229 (aspartic acid → asparagine), 2029 (threonine → isoleucine) and 2050 (asparagine → aspartic acid), wherein the numbering of the amino acid residues is based upon the numbering of the amino acid residues in the RSV wild-type strain RSV 2B (SEQ ID NO:2).

3. A vaccine comprising an isolated, recombinantly-generated, attenuated RSV subgroup B according to Claim 1 and a physiologically acceptable carrier.

The examiner relies on the following references:

Randolph et al. (Randolph U.S.)	5,932,222	Aug. 3, 1999
Randolph et al. (Randolph EP)	EP 567100	Oct. 27, 1993

Claims 1 and 3 stand rejected as follows:

• under 35 U.S.C. § 112, first paragraph, as nonenabled;

• under 35 U.S.C. § 102(e) as anticipated by Randolph U.S.;

• under 35 U.S.C. § 102(b) as anticipated by Randolph EP; and

• for obviousness-type double patenting over claims 7-10 of Randolph U.S.

We affirm the rejections for anticipation and obviousness-type double patenting and do not reach the rejection for nonenablement.

Background

Human respiratory syncytial virus (RSV) is "the primary cause of serious viral pneumonia and bronchiolitis in infants and young children." Specification, page 25. "Early attempts (1966) to vaccinate young children used a parenterally administered formalin-inactivated RSV vaccine. Unfortunately, several field trials of this vaccine revealed serious adverse reactions." Page 5. "Thereafter, two live attenuated RSV mutants were generated by cold passage or chemical mutagenesis. These RSV strains were found to have reduced virulence in seropositive adults. Unfortunately, they proved either over- or underattenuated when given to seronegative infants." Page 7. "Currently, there are no RSV vaccines approved for administration to humans." Id.

"While live, attenuated viruses have highly desirable characteristics as vaccine candidates, they have proven to be difficult to develop. The crux of the difficulty lies in the need to isolate a derivative of the wild-type virus which has lost its disease-producing

potential (i.e., virulence), while retaining sufficient replication competence to infect the recipient and elicit the desired immune response profile in adequate abundance." Page 8.

The RSV genome encodes ten major polypeptides, including an RNA polymerase, which is encoded by the L gene. See pages 27-28. The specification provides a comparison of the RNA polymerase and L gene sequences from two wild-type RSV strains (2B and 18537) with those from two vaccine strains (2B33F and 2B20L). See page 33 and SEQ ID NOs 1-8. See also page 53 ("The 2B33F and 2B20L strains . . . are described in U.S. Serial No. 08/059,444.")[1] and page 37 (stating that the 2B33F and 2B20L strains were deposited with the American Type Culture Collection).

When Appellants compared the sequence of the wild-type strain 2B to those of the attenuated (vaccine) strains, they found that the amino acid sequence encoded by the L gene of strains 2B20L and 2B33F differed in three and four positions, respectively, compared to the wild-type strain. See page 54, lines 17-32, and Tables 21 and 22 (pages 90-91).

Discussion

1. Anticipation

The claims stand or fall together, since Appellants have not argued the claims separately. We will consider claim 1 as representative; claim 3 will stand or fall with claim 1. Claim 1 is directed to an isolated, recombinantly generated, attenuated RSV virus having at least one of the mutations disclosed in the specification to have been found in either or both of the vaccine strains 2B20L and 2B33F.

[1] Application 08/059,444 issued as the Randolph patent (U.S. Patent 5,932,222) cited by the examiner.

The examiner rejected claims 1 and 3 as anticipated by both Randolph U.S. and Randolph EP. The examiner noted that both Randolph references disclose the isolation and characterization of the 2B33F and 2B20L strains of RSV and disclose that the strains were deposited with the ATCC. See the Examiner's Answer, pages 8-9. The examiner reasoned that "[t]he mere recitation of the actual nucleotide sequences (see instant specification tables 21-22) that are inherently possessed by the attenuated viruses in the prior art, does not cause the claim drawn to those things to distinguish over the prior art." Id.

We agree with the examiner's reasoning and conclusion. "The discovery of a new property . . . of a previously known composition, even when that property . . . [is] unobvious from the prior art, can not impart patentability to claims to the known composition." In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). Here, RSV strains 2B33F and 2B20L were known. See Randolph U.S., column 8, lines 52-61, and Randolph EP, page 6, lines 54-58 (both Randolph references refer to the strains as 2Bp33F and 2Bp20L, but the ATCC deposit designations are the same as those given in the instant specification for 2B33F and 2B20L). Claim 1 reads on the known strains and is therefore anticipated.

It is true that neither Randolph reference discloses the nucleotide sequence of the 2B33F and 2B20L strains. Appellants may well have been the first to discover the nucleotide sequences of the known strains, and to have discerned the manner in which those sequences differ from that of the wild-type strain. The nucleotide sequence of a viral strain, however, is an inherent property of the viral strain. Appellants' claim

therefore does not define a new composition, but an old composition with a property that was previously unknown but inherently present.

"In response to the PTO's asserted prima facie case the applicant may argue that the inference of lack of novelty was not properly drawn, for example if the PTO did not correctly apply or understand the subject matter of the reference, or if the PTO drew unwarranted conclusions therefrom. However, when the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." Spada, 911 F.2d at 708, 15 USPQ2d at 1658.

Appellants concede that "Randolph U.S. discloses the existence of the 2B wild-type and the 2B33F and 2B20L vaccine strains." Appeal Brief, page 21. However, Appellants disagree with the examiner's position that "depositing of the 2B33F and 2B20L vaccine strains (but not the 2B wild-type strain) means that Randolph U.S. inherently possesses the sequences claimed by Appellants." Id., page 22.[2] Appellants argue that "a distinction must be drawn between the physical characteristics of a product and its structure. In the case of a virus containing one or more attenuating mutations, the physical characteristics include the phenotype of the virus, such as attenuation, growth and immunogenicity. In contrast, the structure is its genotype, the specific nucleotide sequence which encodes a specific amino acid sequence." Id., pages 22-23.

Appellants are correct that a distinction can be drawn between the characteristics of a product and its structure, but that distinction does not help their case. When a

[2] Appellants rely on the same argument with respect to Randolph EP. See the Appeal Brief, page 29.

composition is old, it is not rendered patentable by discovery of either a new characteristic or a new structure. See Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999) ("An inherent structure, composition or function is not necessarily known. . . . Insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation." (emphasis added)); Spada, 911 F.2d at 709, 15 USPQ2d at 1658 ("When the claimed compositions are not novel they are not rendered patentable by recitation of properties, whether or not these properties are shown or suggested in the prior art." (emphasis added)).

Appellants argue that In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977), and In re Schreiber, 128 F.3d 1473, 44 USPQ2d 1429 (Fed. Cir. 1997), which were cited by the examiner, are not applicable here. Appeal Brief, page 23. Appellants argue that, applying the appropriate case law,

> it should be held here that Randolph U.S. also did not provide an adequate written description of the structure, that is, the sequence of the RSV B strains, by virtue of the deposited materials plus characterization of their phenotypic properties.

Appeal Brief, page 25. Appellants argue that "Randolph U.S. did not enable the claimed invention in this application on appeal." Id.

This argument is not persuasive. First, the Randolph references disclose that the 2B33F and 2B20L strains were deposited at the American Type Culture Collection under the provisions of the Budapest Treaty. See Randolph U.S., column 8, and Randolph EP, page 6. The strains were therefore apparently available to anyone skilled in the art who wished to acquire a sample and sequence the genomes for themselves. An appropriate deposit can be relied on to meet both the enablement and description

requirements of 35 U.S.C. § 112. See Ajinomoto Co. v. Archer-Daniels-Midland Co., 228 F.3d 1338, 1345-1346, 56 USPQ2d 1332, 1337-38 (Fed. Cir. 2000) ("The deposit of biological organisms for public availability satisfies the enablement requirement for materials that are not amenable to written description."); Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 965, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002) ("[R]eference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, para 1.").

In addition, the disclosures in a prior art patent are presumed to be enabled and the applicant bears the burden of proving otherwise. See Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). Appellants have not provided sufficient evidence to support their position that, despite the availability of the 2B33F and 2B20L strains, the Randolph references were nonenabling because they did not disclose the inherent sequence of the strains.

Finally, Appellants argue that "Appellants' Claims recite that the attenuated RSV strains are recombinantly-generated." Reply Brief, page 6.

As we understand it, Appellants' point is that claim 1 is directed to a virus that is made recombinantly, which Randolph's virus was not. Again, however, Appellants have provided no evidence that the claimed virus differs in any way from the virus disclosed by Randolph. The "recombinant" language of claim 1 is at best a product-by-process limitation that defines the product by the method in which it is made. However, "[t]he patentability of a product does not depend on its method of production. If the product in

a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). Here, the product of claim 1 appears to be the same as the prior art product, and therefore the claim is unpatentable.

The rejections of claim 1 under 35 U.S.C. §§ 102(b) and 102(e) are affirmed. Claim 3 falls with claim 1.

2. Obviousness-type double patenting

The examiner rejected claims 1 and 3 "under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim[s] 7-10 of U.S. Patent 5,932,222." Examiner's Answer, page 10. We will affirm this rejection.

Again, the claims stand or fall together. For purposes of this rejection, we will consider claim 3 as representative.[3] Claim 1 will stand or fall with claim 3. Claim 3 is directed to a vaccine (i.e., a composition) comprising an RSV virus defined by claim 1 and a physiologically acceptable carrier.

Claim 8 of the Randolph U.S. patent is directed to a "pharmaceutical composition" comprising one of three RSV strains, two of which are 2B33F and 2B20L (VR 2364 and VR 2368, respectively), and a pharmaceutically acceptable carrier. Randolph U.S. states that the disclosed "[p]harmaceutical compositions . . . are

[3] The examiner relied on claims of the Randolph U.S. patent that are directed to pharmaceutical compositions rather than claims directed to viruses per se. Since instant claim 3 is directed to a composition, we will consider it to be representative for purposes of this rejection. We note, however, that Randolph U.S. also contains claims directed to the 2B33F and 2B20L viral strains themselves (e.g., claims 13 and 15).

especially useful as vaccines" (abstract) and therefore the Randolph U.S. claims reasonably appear to define a vaccine composition.

"Obviousness-type double patenting is a judge-made doctrine that prevents an extension of the patent right beyond the statutory time limit. It requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent." In re Berg, 140 F.3d 1428, 1431, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998). "[A] later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim." Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 971, 58 USPQ2d 1869, 1880 (Fed. Cir. 2001).

Since 2B33F and 2B20L are species within the genus defined by instant claim 1, claim 8 of the Randolph U.S. patent defines two species of composition that fall within the generic composition of instant claim 1. Since the later genus claim (instant claim 1) is anticipated by the earlier species claim (Randolph U.S. claim 8), it is not patentably distinct from the earlier claim. The examiner's rejection for obviousness-type double patenting is affirmed.

Appellants argue that the rejections are improper because "[f]or the same reasons set forth with respect to the Section 102 discussion above, . . . the sequences of the 2B33F and 2B20L strains are not inherently disclosed by Randolph U.S., even with the deposit of those strains." Appeal Brief, pages 31-32.[4] This argument is addressed above and is no more persuasive in the context of obviousness-type double patenting.

[4] Appellants also argue that the examiner inappropriately entered this rejection for the first time in the final rejection. We take no position on whether the examiner acted properly in making the rejection final, because that issue can be reviewed only by petition, not appeal. See MPEP § 706.07(c).

Appellants also argue that even if Randolph U.S. inherently disclosed the claimed virus strains, "the Examiner's rejection on the ground of obviousness based on inherency of sequences in Randolph U.S. is not appropriate as a matter of law. As was stated in W.L. Gore & Associates, Inc. v. Garlock, Inc., 220 USPQ 303, 314 (Fed. Cir. 1983): 'Inherency and obviousness are distinct concepts.'" Appeal Brief, page 32.

This argument is also unpersuasive. The rejection at issue is not based on obviousness under 35 U.S.C. § 103 but on obviousness-type, or nonstatutory, double patenting. The respective analyses differ in several respects:

> 1. The objects of comparison are very different: Obviousness compares claimed subject matter to the prior art; nonstatutory double patenting compares claims in an earlier patent to claims in a later patent or application;
>
> 2. Obviousness requires inquiry into a motivation to modify the prior art; nonstatutory double patenting does not;
>
> 3. Obviousness requires inquiry into objective criteria suggesting non-obviousness; nonstatutory double patenting does not.

Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1378 n.1, 68 USPQ2d 1865, 1869 n.1 (Fed. Cir. 2003).

Since the instant claims define a genus that encompasses the previously claimed species, a rejection for obviousness-type, or nonstatutory, double patenting is appropriate. The examiner's rejection is affirmed.

3. Enablement

The examiner rejected claims 1 and 3 as nonenabled. Since we have already concluded that claims 1 and 3 are unpatentable on the basis of anticipation and double patenting, we need not decide whether they are also unpatentable as nonenabled. Therefore, we do not reach the issue of enablement.

Summary

We affirm the rejections under 35 U.S.C. §§ 102(b) and 102(e) and the rejection for obviousness-type double patenting, and do not reach the rejection under 35 U.S.C. § 112, first paragraph.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Toni R. Scheiner)
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